DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 22, 2014

Whip Mix Corporation
Mr. John P. Waters
Regulatory Compliance Officer
361 Farmington Avenue
Louisville, KY 40217

Re: K142670
Trade/Device Name: Vericore Zirconia Blanks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: September 18, 2014
Received: September 25, 2014

Dear Mr. Waters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K142670

Indications for Use:
Vericore zirconia blanks are made from pre-sintered zirconium dioxide intended to be used with many CAD/CAM or manual milling machines. Vericore zirconia blanks are biocompatible and designed to fabricate;

- Zirconia Substructures
- Restorations (Including inlays, onlays, and veneers)
- Crown Framework in the Anterior and Posterior regions
- Bridge Framework in the Anterior and Posterior regions

Prescription Use___X_____ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CRR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Special) 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

Date Prepared: 9/18/2014

1. APPLICANT

Whip Mix Corporation
361 Farmington Avenue
Louisville, KY 40217

PHONE: 502-634-5357
FAX: 502-634-4512
EMAIL: jwaters@whipmix.com

2. SUBMITTER and CONTACT

John P. Waters
Regulatory Compliance Officer & Official Correspondent for
Whip Mix Corporation
361 Farmington Avenue
Louisville, KY 40217

PHONE: 502-634-5357
FAX: 502-634-4512
EMAIL: jwaters@whipmix.com
DATE: 9/18/2014

3. DEVICE NAME

Vericore Zirconia Blanks

4. COMMON OR USUAL NAME AND CLASSIFICATION

Powder, Porcelain
Regulation Number: **872.6660**
Product Code: **EIH**
Classification: **Class II**

5. PREDICATE DEVICE INFORMATION

Whip Mix Vericore Zironia Blanks **(K140877)**

6. DEVICE DESCRIPTION

Vericore Zirconia Blanks is a device made from pre-pressed and pre-sintered zirconia powder. It is available in various shades, shapes, and sizes to accommodate the customers CAD/CAM or manual milling equipment/strategies and is not machine specific. Vericore Zirconia Blanks are made from a biocompatible zirconia powder. It is intended to be used by professionals for the fabrication of dental restorations.

7. INTENDED USE

Vericore zirconia blanks are made from pre-sintered zirconium dioxide intended to be used with many CAD/CAM or manual milling machines. Vericore zirconia blanks are biocompatible and designed to fabricate;

- Zirconia Substructures
- Restorations (Including inlays, onlays, and veneers)
- Crown Framework in the Anterior and Posterior regions
- Bridge Framework in the Anterior and Posterior regions

8. SUBSTANTIAL EQUIVALENCE WITH PREDICATE DEVICES

Whip Mix Corporation	**Whip Mix Corporation**
Proposed new device	Predicate Device
Vericore Zirconia Blanks	Vericore Zirconia Blanks
Class II Device	Class II Device
510(k) Pending	510(k) K140877
Product Code EIH	**Product Code** EIH
Regulation Number- 872.6660	**Regulation Number-** 872.6660
Material- Biocompatible zirconia powder manufactured by Tosoh Corporation	**Material-** Biocompatible zirconia powder manufactured by Tosoh Corporation
Indications For Use Vericore zirconia blanks are made from pre-sintered zirconium dioxide intended to be used with many CAD/CAM or manual milling machines. Vericore zirconia blanks are biocompatible and designed to fabricate; - Zirconia Substructures - Restorations (Including inlays, onlays, and veneers) - Crown Framework in the Anterior and Posterior regions - Bridge Framework in the Anterior and Posterior regions -	**Indications For Use** Vericore zirconia blanks are made from pre-sintered zirconium dioxide intended to be used with many CAD/CAM or manual milling machines. Vericore zirconia blanks are biocompatible and designed to fabricate; - Zirconia Substructures - Restorations (Including inlays, onlays, and veneers) - Crown Framework in the Anterior and Posterior regions - Bridge Framework in the Anterior and Posterior regions

9. BENCH TESTING

Flexural strength and chemical solubility tests were performed in accordance with ISO 6872 and all tests passed. Non-clinical testing for density was performed as well and the results are recorded in the proposed labeling.

10. BIOCOMPATIBILITY

The product is biocompatible because the predicate device was tested in accordance with ISO 10993-10, 10993-3, and 10993-5. No further biocompatibility tests are necessary because Whip Mix Vericore Blanks are made from the same powder as the predicate.

11. SAFETY AND EFFECTIVENESS CONCLUSION

This additional of the Ultra-Translucent Vericore® Zirconia Blanks are substantially equivalent to Whip Mix Vericore Zirconia Blanks material in safety and effectiveness when used in accordance with the instructions for use. Both have identical Indications for Use, use the same raw material, and are biocompatible.